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EXAMINER

KAPADIA, MILAN S

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/428,035

Applicant(s)

MCGRADY ET AL.

Examiner

Milan S Kapadia

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Notice to Applicant

1. This communication is in response to the responses filed on 5/10/02 and 1/28/03. Claims 1-28 are pending.

2. After re-considering Applicant's Appeal brief filed 1/28/03 and the previous Office Action mailed 8/5/02, the finality of that action is withdrawn. The Examiner made some inadvertent mistakes concerning the rejection of claims, in particular with respect to groupings of claims as § 102 or § 103. As a result, the Examiner is issuing the present Office Action to make the record more clear and complete.

Claim Objections

3. Claim 22 is objected to because of the following informalities: (e) should apparently be (h) in line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 4, 6-8, 11-13, 16-18, and 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Gombrich et al. (4,857,716) for substantially the same reasons set forth in the previous Office Actions (paper numbers 5 and 7). Further reasons appear below.

(A) As claim 4, Gombrich discloses a patient identification system comprising the steps of:

(a) storing patient data in memory devices in operative connection to a programmed general purpose computer (Gombrich; col. 2, lines 5-8, col. 8, lines 10-15, and fig. 1);

(b) printing on a sheet of bar code labels, patient specific bar code identifiers and the patient's name (Gombrich; col. 12, lines 66-67, col. 13, lines 1-2, and fig. 4; The examiner interprets this as a form of report generation);

(c) scanning patient specific bar code identifiers from a patient chart (Gombrich; col. 13, lines 32-37);

(d) entering and recording a drug prescription as being approved and ready for dispensing (Gombrich; col. 14, lines 22-25; The examiner interprets Gombrich's "being approved" to be a form of "taking"); and

(e) recording the administration of items to patients (Gombrich; col. 16, lines 3-4; The examiner interprets Gombrich's "administration" to be a form of "having been given.") Also note, an embodiment of the bar code reading device might include a programmed microprocessor and its associated memory and real time

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clock mounted in a hand held housing wherein a key pad is provided for entry of data and a LCD display will be provided for displaying information (Gombrich; col. 11, lines 4-44 and figures 1 and 10-12).

(B) As per claim 6, Gombrich discloses:

(e) an embodiment of the bar code reading device might include a programmed microprocessor and its associated memory and real time clock mounted in a hand held housing wherein a key pad is provided for entry of data and a LCD display will be provided for displaying information (Gombrich; col. 11, lines 4-44 and figures 10-12).

(C) As per claims 7 and 8, Gombrich discloses:

(e) a means for scanning the patient identifier bar code on the patient's identification bracelet (Gombrich; figure 3 and col. 15, lines 12-16).

(D) As per claims 11 and 12, Gombrich discloses:

(a) a means for storing a prescription prescribing drug treatment for the patient (Gombrich; col. 13, lines 32-39);

(b) generating bar code labels for drugs in prescription with a printer (Gombrich; col. 14, lines 7-15); and (The examiner interprets this as a form of report generation)

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(e) scanning drug bar codes during administration with a bar code reader
(Gombrich; col. 15, lines 58-62).

(E) As per claim 13, Gombrich discloses an alternate embodiment of the invention consisting of a portable handheld terminal used in conjunction with a wall mounted base station. The base station includes a means for communicating with the portable handheld terminal and the computer system (Gombrich; col. 23, lines 51-68 and figures 30-34).

(F) As per claim 16, Gombrich reference discloses a patient identification system comprising the steps of:

- (a) storing patient data in memory devices in operative connection to a programmed general purpose computer (Gombrich; col. 2, lines 5-8);
- (b) a means for storing a prescription prescribing drug treatment for the patient (Gombrich; col. 13, lines 32-39);
- (c) generating custom bar code labels for drugs in prescription with a printer (Gombrich; col. 14, lines 7-15); and (The examiner interprets this as a form of report generation);
- (d) scanning the patient's identification bar code on the patient's prescription with a bar code reader (Gombrich; col. 13, lines 57-61 and col. 14, lines 22-26);
- (e) scanning the drug identifier bar code on the drug package with a bar code reader (Gombrich; col. 14, lines 22-24);

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(f) a means for entering and recording a drug prescription as being approved and ready for dispensing (Gombrich; col. 14, lines 22-25); (The examiner interprets Gombrich's "being approved" to be a form of "taken for use.")

(g) a means for the administering the prescribed drug (Gombrich; col. 15, lines 9-67); and

(h) a means for recording the administration of items to patients (Gombrich; col. 16, lines 3-4). (The examiner interprets Gombrich's "administration" to be a form of "has been used.")

(G) As per claim 17 Gombrich discloses:

(c) generating custom bar code labels for drugs in prescription with a printer (Gombrich; col. 14, lines 7-15); and (The examiner interprets this as a form of report generation)

(d) scanning drug identifier bar code on the drug package with a bar code reader (Gombrich; col. 14, lines 22-26).

(H) As per claim 18, Gombrich teaches recording the administration of items to patients (Gombrich; col. 16, lines 3-4; The examiner interprets Gombrich's "administration" to be a form of "having been given.") Also note, an embodiment of the bar code reading device might include a programmed microprocessor and its associated memory and real time clock mounted in a hand held housing wherein a key

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pad is provided for entry of data and a LCD display will be provided for displaying information (Gombrich; col. 11, lines 4-44 and figures 10-12).

(I) As per claims 22, 23, and 25, Gombrich discloses:

(h) an embodiment of the bar code reading device might include a programmed microprocessor and its associated memory and real time clock mounted in a hand held housing (Gombrich; col. 11, lines 4-44 and figures 10-12). (The examiner interprets the nurse using this device as being adjacent to bedside of patient).

(J) As per claim 24, Gombrich discloses:

(h) a bar code reader for scanning the patient identifier bar code on the patient's identification bracelet (see figure 3 and Gombrich; col. 15, lines 12-16).

(K) As per claim 26, Gombrich reference discloses a patient identification system comprising the steps of:

(a) storing patient data in memory devices in operative connection to a programmed general purpose computer (Gombrich; col. 2, lines 5-8);

(b) a means for storing a prescription prescribing drug treatment for the patient (Gombrich; col. 13, lines 32-39);

(c) scanning the patient's identification bar code on the patient's prescription with a bar code reader (Gombrich; col. 13, lines 57-61);

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(d) scanning the drug identifier bar code on the drug package with a bar code reader (Gombrich; col. 14, lines 22-24);

(e) a means for entering and recording a drug prescription as being approved and ready for dispensing (Gombrich; col. 14, lines 22-25); (The examiner interprets Gombrich's "being approved" to be a form of "taken for use.")

(f) a means for the administering the prescribed drug (Gombrich; col. 15, lines 9-67); and

(g) a means for recording the administration of items to patients (Gombrich; col. 9, lines 54-67 and col. 16, lines 3-4; The examiner interprets Gombrich's "administration" to be a form of "has been used.") Also note, Gombrich teaches terminals that can located locally and remotely as required, including at nurse's stations (Gombrich; col. 8, lines 23-28; The Examiner interprets the nurse's station as being "positioned in generally fixed relation adjacent a bedside area of the one patient.")

(L) As per claim 27, Gombrich discloses the transmission of data between a portable bar code reading device and remote terminals (Gombrich; col. 9, lines 57-65 and figure 6).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 5, 14-15, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombrich, et al. (4,857,716) as applied to claim 16 above and given in view of Moulding, Jr. et al. (4,604,847), for substantially the same reasons set-forth in the previous Office Action (paper number 7). Further reasons appear below.

(A) As per claim 1, Gombrich discloses a patient identification system comprising the steps of:

(a) storing patient data in memory devices in operative connection to a programmed general purpose computer (Gombrich; col. 2, lines 5-8, col. 8, lines 10-15, and fig. 1);

(b) printing on a sheet of bar code labels, patient specific bar code identifiers and the patient's name (Gombrich; col. 12, lines 66-67, col. 13, lines 1-2, and fig. 4; The examiner interprets this as a form of report generation);

(c) scanning patient specific bar code identifiers from a patient chart (Gombrich; col. 13, lines 32-37);

(d) entering and recording a drug prescription as being approved and ready for dispensing (Gombrich; col. 14, lines 22-25; The examiner interprets Gombrich's "being approved" to be a form of "taking."); and

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(e) recording the administration of items to patients (Gombrich; col. 16, lines 3-4;

The examiner interprets Gombrich's "administration" to be a form of "having been given.")

Gombrich fails to expressly teach a report that includes patient identifiers and machine-readable indicia corresponding to at least one item prescribed for the patient . However, this feature is old and well known in the art, as evidenced by Moulding's teachings with regards to this limitation (Moulding; col. 2, lines 16-22 and col. 10, lines 56-58; the examiner interprets "means for recording" as a form of "generating a report.") It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Gombrich with Moulding's teaching with regards to this limitation, with the motivation of indicating the characteristics of the medicine contained in a package (Moulding; col. 1, lines 62-64).

(B) As per claim 2, Gombrich discloses:

(a) a means for storing a prescription prescribing drug treatment for the patient (Gombrich; col. 13, lines 32-39);

(d) scanning drug identifier bar codes with a bar code reader (Gombrich; col. 14, lines 22-25).

(C) As per claims 3 and 5 Gombrich discloses:

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(e) a means for scanning drug bar codes during administration (Gombrich; col. 15, lines 58-62; The examiner interprets the nurse as being adjacent to the bed of the patient).

(D) As per claim 14, Gombrich discloses a patient/drug schedule being generated upon drugs being approved and ready for dispensing and prior to administration (Gombrich; col. 14, lines 51-61; The examiner interprets this as a form of report generation)

(E) As per claim 15, Gombrich discloses a system for the control of controlled drugs such as narcotics comprising the steps of:

(a) a means for reporting and controlling accessibility to narcotics (Gombrich; col. 17, lines 4-5; The examiner interprets this as storing data representative of a plurality of authorized users since only authorized users can obtain the narcotics)

(b) a means for scanning a nurse's badge to identify her to the system (Gombrich; col. 17, lines 8-9); and

(c) a means for checking out drugs from a locked drawer or drug cart and placing them into the nurse's inventory, where it will remain until she administers the drug to the patient (Gombrich; col. 17, lines 11-14; The examiner interprets this as dispensing medical item to user only if authorized and a form of report generation indicative that authorized user has taken drug.)

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(F) As per claim 28, Gombrich teaches printing on a sheet of bar code labels, patient specific bar code identifiers and the patient's name (Gombrich; col. 12, lines 66-67, col. 13, lines 1-2, and fig. 4; The examiner interprets this as a form of report generation) but fails to expressly teach a report that includes patient identifiers and machine-readable indicia corresponding to at least one item prescribed for the patient. However, this feature is old and well known in the art, as evidenced by Moulding's teachings with regards to this limitation (Moulding; col. 2, lines 16-22 and col. 10, lines 56-58; the examiner interprets "means for recording" as a form of "generating a report.") It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Gombrich with Moulding's teaching with regards to this limitation, with the motivation of indicating the characteristics of the medicine contained in a package (Moulding; col. 1, lines 62-64).

8. Claims 9-10 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombrich, et al. (4,857,716) as applied to claim 7 above.

(A) As per claims 9 and 10, Gombrich discloses the placing of patient identification bar codes on the patient's identification bracelet (col. 8, lines 66-68). Gombrich fails to expressly disclose the placement of patient identifier labels on the patient bed or on a bedside chart. It is respectfully submitted, that one having ordinary skill in the art at the time of the invention would have found it obvious to have placed patient identifier labels

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on the patient's bed or bed side chart with the motivation of providing such data in a highly visible location in case of patient bracelet misplacement or damage.

(B) As per claim 19, Gombrich reference discloses a patient identification system comprising the steps of:

- (a) storing patient data in memory devices in operative connection to a programmed general purpose computer (Gombrich; col. 2, lines 5-8);
- (b) a means for storing a prescription prescribing drug treatment for the patient (Gombrich; col. 13, lines 32-39);
- (c) scanning the patient's identification bar code on the patient's prescription with a bar code reader (Gombrich; col. 13, lines 57-61);
- (d) scanning the drug identifier bar code on the drug package with a bar code reader (Gombrich; col. 14, lines 22-24);

Gombrich discloses the placing of the drug, upon approval and ready for dispensing and prior to administration, in the patient's drug cart (col. 14, lines 51-62). Gombrich fails to expressly disclose the dispensing of one medical item from a medical item dispenser. It is respectfully submitted, that one having ordinary skill in the art at the time of the invention would have found it obvious to dispense the one medical item from a medical dispenser after scanning the drug identifier and patient bar codes with the motivation of providing drug inventory control.

(C) As per claim 20, Gombrich reference discloses a patient identification system

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comprising the steps of:

- (a) storing patient data in memory devices in operative connection to a programmed general purpose computer (Gombrich; col. 2, lines 5-8);
- (b) a means for storing a prescription prescribing drug treatment for the patient (Gombrich; col. 13, lines 32-39);
- (c) scanning the patient's identification bar code on the patient's prescription with a bar code reader (Gombrich; col. 13, lines 57-61);
- (d) scanning the drug identifier bar code on the drug package with a bar code reader (Gombrich; col. 14, lines 22-24);
- (e) a means for entering and recording a drug prescription as being approved and ready for dispensing (Gombrich; col. 14, lines 22-25); (The examiner interprets Gombrich's "being approved" to be a form of "taken for use.")
- (f) a means for the administering the prescribed drug (Gombrich; col. 15, lines 9-67); and
- (g) a means for recording the administration of items to patients (Gombrich; col. 16, lines 3-4). (The examiner interprets Gombrich's "administration" to be a form of "has been used.")

Gombrich discloses the placing of the drug, upon approval and ready for dispensing and prior to administration, in the patient's drug cart (col. 14, lines 51-62). Gombrich fails to expressly disclose the dispensing of one medical item from a medical item dispenser. It is respectfully submitted, that one having ordinary skill in the art at the time of the invention would have found it obvious to

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dispense the one medical item from a medical dispenser after scanning the drug identifier and patient bar codes with the motivation of providing drug inventory control.

(D) As per claim 21, Gombrich discloses a system for the control of controlled drugs such as narcotics comprising the steps of:

(a) a means for reporting and controlling accessibility to narcotics (Gombrich; col. 17, lines 4-5); (The examiner interprets this as storing data representative of a plurality of authorized users since only authorized users can obtain the narcotics)

(b) a means for scanning a nurse's badge to identify her to the system (Gombrich; col. 17, lines 8-9);

(c) a means for checking out drugs from a locked drawer or drug cart (Gombrich; col. 17, line 11); and (The examiner interprets this as dispensing item only if user corresponds to one authorized user)

(d) a means for placing narcotic drug into the nurse's inventory (Gombrich; col. 17, lines 12-14). (The examiner interprets this as storing data representative that the medical item has been taken by the one authorized user).

Response to Arguments

9. Applicant's arguments with respect to amended claims 1 and 16 have been considered but are moot in view of the new ground(s) of rejection.

(A) At pages 16-18 of the 5/10/02 communication, Applicant argues each of the applied references individually.

In response, the Examiner respectfully submits that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In particular, the teachings that Applicant argues are missing from the Gombrich reference are clearly disclosed in the respective teachings of Moulding, when considered collectively with that of Gombrich, as discussed in detail within a prior Office Action (paper number 5) and in the preceding rejections, and incorporated herein.

Further, the features newly added and entered in the amendment filed 5/10/02, they have been shown to be fully disclosed by or obvious in view of the collective teachings of Gombrich and/or Moulding, as discussed above in detail within the preceding sections of the present Office Action.

In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

10. Applicant's arguments filed 5/10/02 have been fully considered but they are not persuasive. Applicant's arguments will be addressed herein below in the order in which they appear in the response filed 5/10/02.

(A) At page 16 of the 5/10/02 response, Applicant argues that "printing on a sheet of bar code labels, patient specific bar code identifiers and the patient's name' and 'generating bar code labels for drugs in prescription with a printer'" are not "forms of report generation" in reference to claim 1. In response, the examiner respectfully notes that it is commonly known in the art that a report is defined as the presentation of information about a given topic, typically in printed form (See Microsoft computer dictionary 5th edition, page 450, attached at the end of the previous office action). Thus, it is respectfully submitted, that "printing on a sheet of bar code labels, patient specific bar code identifiers and the patient's name" and "generating bar code labels for drugs in prescription with a printer" are indeed form of "report generation."

As per the Applicant's arguments that "Gombrich would not teach generating a report, where the report includes both machine readable indicia corresponding to at least one of the patients and machine readable indicia corresponding to at least one item prescribed for the patient." In response, the examiner respectfully submits, that as shown above in the rejection of amended claim 1, the combined system of Gombrich and Moulding do teach this limitation.

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(B) At page 17 of the 5/10/02 response, Applicant argues that "the bar code reader taught by Gombrich cannot constitute the recited portable terminal," in reference to claim 4. In response, the examiner respectfully notes that it is commonly known in the art that a terminal is defined as a combination of a video adapter, monitor, and a keyboard (See Microsoft computer dictionary 5th edition, page 515, attached at the end of the previous office action). Gombrich teaches that the "bar code reader devices has a key pad" and "LCD display for displaying information and status" (Gombrich; col. 11, lines 10-15). It is respectfully submitted that the bar code reader therefore is a form of "portable terminal."

As per the Applicant's arguments that the "bar code reader is not capable of receiving inputted data representative of giving of a medical item to a patient." In response, the examiner respectfully submits that the Applicant ignores that the "bar code reading device" is used for "receiving inputted data representative of the giving of a medical item to a patient" as shown in the prior Office Action (paper number 5, section 4(A), page 3). See also col. 16, lines 3-8 of Gombrich.

As per the Applicant's arguments that the "bar code reader is not capable of storing data representative of giving of a medical item to a patient." In response, the examiner respectfully submits that the Applicant ignores that the "bar code reading device" has memory as shown in the prior Office Action (paper number 5, section 4(D), page 4), and therefore is "capable of storing data representative of giving of a medical item to a patient." See also col. 11, lines 4-44 of Gombrich

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As per the Applicant's arguments that the "bar code reader is not capable of transferring data representative of giving of a medical item from the bar code reader to the computer." In response, the examiner respectfully submits that Gombrich does teach that data is transferred from the bar code reading device and the computer (Gombrich col. 12, lines 48-51).

(C) At page 18 of the 5/10/02 response, Applicant argues that "a bar code label on a drug package is not a report" in reference to claim 16. In response, the examiner respectfully notes that it is commonly known in the art that a report is defined as the presentation of information about a given topic, typically in printed form (See Microsoft computer dictionary 5th edition, page 450, attached at the end of the previous office action). Thus, it is respectfully submitted, that "a bar code label on a drug package" is indeed form of "a report."

As per the Applicant's arguments that "Gombrich does not teach a report including both machine readable indicia indicative of a medical item prescribed for a patient and further information indicative of the patient." In response, the examiner respectfully submits, that Gombrich does teach this features. At col. 14, lines 7-15, Gombrich teaches that a custom bar codes can be generated. These custom bar codes not only correspond to the prescribed medication but also correspond to a patient's identity. It is respectfully a bar code that corresponds to both a medical item prescribed for a patient and a patient's name, does meet the limitation "a report including machine

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readable indicia indicative of a medical item prescribed for a patient, where the report further includes information indicative of the patient.”

(D) At pages 18-20 of the 5/10/02 response, Applicant argues that certain features of the claimed invention as recited in claims 19 and 20 are not taught by the applied reference.

In response, the Examiner respectfully notes that the cited reference was never applied as a reference under 35 U.S.C. 102 against amended claims 19, and 20. As such, the Examiner respectfully submits that the issue at hand is not whether the applied prior art specifically teaches the claimed features, *per se*, but rather, whether or not the prior art, when taken in combination with the knowledge of average skill in the art, would put the artisan in possession of these features. Regarding this issue, it is well established that references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

- (i) obviousness does not require absolute predictability;
- (ii) non-preferred embodiments of prior art must also be considered; and

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(iii) the question is not express teaching of references, but what they would suggest.

According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. In *In re Bode*, 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein.

According to *Ex parte Berins*, 168 USPQ 374 (Bd. Appeals), there is no statutory limitation as to the number of references that may be used to demonstrate obviousness...not what references expressly state but what they would reasonably suggest to one of ordinary skill in the art. In *In re Conrad*, 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

In the instant case, Gombrich discloses the object of one embodiment of the present invention is to provide automatic billing and/or inventory control (Gombrich; col. 2, lines 57-60). The Examiner admitted that Gombrich fails to expressly teach a medical item dispenser. However, at col. 16, line 67-col. 17, line 35, Gombrich teaches a locked drug cart that in response to reading machine readable indicia on a report, dispenses at least one medical item. Since medical item dispensers that perform similar functions are well known in the art (See Applicant's supplied art, McLaughlin et al. (4,811,764) and Carter (4,967,928)), it is respectfully submitted that using a medical item dispenser is obvious within the system of Gombrich.

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As such, it is respectfully submitted that Applicant appears to view the applied references in a vacuum without considering the knowledge of average skill in the art.

Furthermore, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

(E) At pages 20-21 of the 5/10/02 response, Applicant argues that "Gombrich does not teach bedside positioning of terminals" as recited in claim 26. In response, the examiner respectfully submits that the Applicant ignores that the terminals might be located remotely as required, including at nurse's stations (Gombrich; col. 8, lines 26-30). Since it is readily apparent that the data stored on a terminal typically is gathered and updated for a unique individual within a hospital environment, it would have required no hindsight to locate the terminal as close as possible to the individual, such as bedside.

Furthermore, as presently claimed, there is no requirement for the terminal to be positioned at a bedside. As presently claimed, "a bedside terminal positioned in a generally fixed relation adjacent a bedside area of the one patient" only requires the

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terminal to be "in a generally fixed relation adjacent" to a bedside and not positioned "at" a bedside area. It is well known that the term adjacent means close proximity but not necessarily contact (See Webster's dictionary). As such, it is respectfully submitted that a terminal at a nurse's station does meet this limitation.

In addition, as presently claimed, , "a bedside terminal positioned in a generally fixed relation adjacent a bedside area of the one patient" does not require the terminal to be at a fixed location. It is unclear what the Applicant means by "generally fixed." Gombrich teaches that the portable bar code reading device can be attached to the patient's bed or chart (Gombrich; col. 8, lines 59-65) and col. 11, lines 55-58). It is unclear if this constitutes Applicant's "generally fixed" limitation.

(F) With respect to claims 2, 9, 12, 14, 15, 21, and 25 the Examiner is concerned that, aside from merely alleging that certain claimed features are not obvious from Gombrich and Moulding essentially in the form of blanket statements, Applicant does not point to any specific distinction(s) between the features disclosed in the references and the features that are presently claimed. In particular, 37 CFR 1.111(b) states, "A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the reference does not comply with the requirements of this section." Applicant has failed to specifically point out how the language of the claims patentably distinguishes them from the applied references. Also, arguments or conclusions of Attorney cannot take the place of evidence. *In re Cole*, 51 CCPA 919, 326 F.2d 769, 140 USPQ 230 (1964); *In*

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re Schulze, 52 CCPA 1422, 346 F.2d 600, 145 USPQ 716 (1965); *Mertizner v. Mindick*, 549 F.2d 775, 193 USPQ 17 (CCPA 1977).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Milan S Kapadia whose telephone number is 703-305-

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3887. The examiner can normally be reached on Monday through Thursday, 8:30 A.M. to 6:00 P.M. In addition the examiner can be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600

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April 21, 2003